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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
HAWES, PILI ASABI	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,970	JAO ET AL.	
	Examiner	Art Unit	
	Pili A. Hawes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31,33-37 and 48-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31,33-37 and 48-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Summary

Claims 31, 33-37, 48-63 are pending in this action. Claims 31, 33-37, 48-63 are rejected.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31, 33-37, 48-63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 11/024329. Although the conflicting claims are not identical, they are not patentably distinct from each other because application '329 claims a dosage form comprising topiramate, a surfactant, and hydrophilic polymers. The claims recite the same polymers and surfactants as the instant application, in the same range or percentages. The only difference between '329 and the instant application is that '329 recites the limitation that the active ingredient is in granule form. However it would be obvious to one of ordinary skill in the art to form granules for the

dosage form of the instant application because granules are more easily able to be formed into compressed tablets or incorporated into capsule dosage forms.

Claims 1-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 11/024330. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of application '330 recite the same dosage form as the instant claims, the same surfactants and structural polymers, and the overlapping ratios or percentages of the ingredients as in the instant claims. The only difference is the claims of application '330 recite a pharmaceutical agent of low solubility, while the instant claims recite a particular low solubility drug, topiramate. It would be obvious to one of ordinary skill in the art to substitute topiramate into the composition because topiramate is a low solubility pharmaceutical agent.

Claims 31, 33-37, 48-63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27, 32-39 of copending Application No. 11/024378. Although the conflicting claims are not identical, they are not patentably distinct from each other because application '378 discloses a controlled release dosage form with the same composition and active ingredients as the instant claims. The only difference is that the amounts of active ingredient are presented as both milligram amounts and percentages of the total weight of the composition in the instant application, while it is only presented in percentages in '378. It would be obvious to one of ordinary skill in the art to adapt the percentages into

milligram amounts and vice versa, to arrive at the composition of the instantly claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 31, 33-37, 48-56, 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Louie-Helm et al. US 2003/0091630.

Louie-Helm discloses a dosage form comprising topiramate, in the form of compressed tablets that contain an erodible, swellable matrix along with the active ingredient [0147]. The matrix particles contain 20 wt % Polyox N-60K and 58.07 wt % Polyox N-80, and 0.5% magnesium stearate [0148]. The swellable erodible matrix is an

osmopolymer. Paragraph 0129 discloses binders used in tablet formulations such as polyvinyl pyrrolidone and hydroxypropylmethylcellulose (page 13). The composition comprises between 10-80% drug [0125]. Polyethylene oxide and polyethylene glycol are synonymous. The reference teaches a composition with two polyethylene oxide polymers of differing molecular weights, with the Polyox-80 having a molecular weight of 200,000 as is claimed in claim 9. Thus Polyox-80 satisfies the structural polymer limitation. Polyethylene oxide is also a surfactant. Thus the teaching of the use of Polyox-80 satisfies the limitation of the solubilizing surfactant as well. The reference further teaches the use of another Polyox polymer of a different molecular weight that could also be a solubilizing surfactant. A preferred embodiment of the invention is for the dosage form to be administered once every 24 hours or more [0026].

Although the reference does not disclose the specific amounts as claimed by applicant in the specific ratios as claimed, one of ordinary skill in the art would be able to determine through routine experimentation the exact percentages and ratios of each ingredient to use in the composition.

Accordingly, it would be obvious to one of ordinary skill in the art at the time the invention was made to prepare an osmotic dosage form comprising topiramate, structural polymers and surfactants and to administer the dosage form once every 24 hours based on the teachings of Louie-Helm. There would be sufficient motivation for one of ordinary skill in the art at the time the invention was made to vary the dosage amounts based on the size, sex, age and gender of the individual to which the dosage from is being administered.

Claims 57, 58, 62, 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Louie-Helm et al. US 2003/0091630 in view of Chen et al. US 6610326.

Louie-Helm has been discussed above. Louie-Helm does not teach specifically Myrj surfactants, but the reference does teach polyoxyethylene glycol.

Chen teaches dosage forms comprising an anti-convulsant (divalproex) (abstract). The reference further teaches myrj types of surfactants (col. 7, line 60).

Accordingly, it would be obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Louie-Helm with Chen and prepare an osmotic dosage form comprising an anticonvulsant such as topiramate, and surfactants such as myrj because Louie-Helm teaches generically using polyoxyethylene glycol and myrj (taught by Chen) are types of these polymers. There would be sufficient motivation for one of ordinary skill in the art at the time the invention was made to use myrj because Chen teaches that they are surfactants and shows they are useful as polishing agents. The motivation for using the surfactants need not be the same as Applicants.

Claims 31, 33-37, 48-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Almarsson et al. US 6699840 B2.

Almarsson discloses oral dosage forms of topiramate with excipients, such as polyvinyl pyrrolidone and hydroxypropyl methylcellulose (col. 18, lines 13-15, 47, 56-57). The reference also teaches using lubricants like polyethylene glycol (col. 19, line 41). The reference further teaches topiramate in controlled release dosage forms and methods for treatment of seizures, epilepsy, tremors, and obesity among others (col. 1, lines 15-18). Such dosage forms are formulated using hydroxypropylmethyl cellulose,

and osmotic systems, such as OROS® (Alza Corporation) (col. 21, lines 25-35). The reference teaches the amount of topiramate in the composition can range from 10 mg-1000 mg (col. 17, lines 60-63). The reference further discloses a specific dosage form of their invention to comprise "a wall defining cavity, the wall having an exit orifice formed or formable therein and at least a portion of the wall being semipermeable; an expandable layer located within the cavity remote from the exit orifice and in fluid communication with the semipermeable portion of the wall; a dry of substantially dry state drug layer located within the cavity adjacent the exit orifice and in direct or indirect contacting relationship with the expandable layer; and a flow promoting layer interposed between the inner surface of the wall and at least the external surface of the drug layer located with tin the cavity, wherein the drug layer comprises a salt of the topiramate" (col. 22, lines 29-44). Claim 25 recites a method for delivering high doses of topiramate by administering the composition for claim 22. Since the composition of claim 22 is anticipated by this reference, the method is also anticipated by this reference since the method step of administering the composition is a necessary step in the method of treating seizures, epilepsy, and tremors as is disclosed in the reference. The limitation "for delivering high doses" is an intended use and does not hold patentable weight since the claim is dependent on a composition claim that does not recite any amounts of topiramate, high or low. The method of enhancing bioavailability by administering the topiramate composition of claim 22 would be an inherent property of the composition when it is administered to a patient in need thereof. In order to treat seizures, epilepsy or tremors the composition would need to be administered to a person suffering from

said diseases. Thus upon administration for the treatment of these ailments the bioavailability would also be increased.

Although the reference does not specifically disclose the particular percentages of each ingredient in the composition, one of ordinary skill in the art would be able to determine through routine experimentation the amounts of each ingredient to add in the composition. One of ordinary skill in the art would have been motivated to increase the amount of the active agent in the composition because the composition is intended for one-a-day controlled release of the active agent. Therefore it would have been obvious to one of ordinary skill that the amount of the active agent in such a composition would need to be greater than the amount in a dosage form that is intended for multiple administrations within a 24 hour period. Once the amount of the active ingredient is determined based on the amount necessary to treat the medical condition being treated, and based on the average patients gender, age, and weight, then the amount of the structural polymer and the solubilizing surfactant can be adjusted to optimize the formulation. The release rate is another property that can be modified based on the amount of the structural polymer and the solubilizing agents added. Thus any release profile desired can be achieved via routine experimentation to select the optimum levels of each ingredient. The generic invention is embodied and described by Almarrason.

Response to Arguments

Applicant's arguments filed 05-15-2006 have been fully considered but they are not persuasive. Applicants argue that Almarrason does not teach the specific percentages of topiramate, surfactant, and structural polymer as claimed by Applicant.

Almarrason teaches using 10-1000 mg of topiramate. Applicants have not shown that this teaching does not satisfy the percentage requirement in the instant claims. Furthemore, such a wide range of dosage amount for the active ingredient taught by Almarrason would provide sufficient motivation to one of ordinary skill in the art to optimize through routine experimentation the amount of each ingredient to make the desired dosage form. From the teaching it is apparent that using high doses of topiramate is envisioned. It would be obvious to one of ordinary skill in the art to adjust the amounts of the solubilizing surfactant and the structural polymer based on the amount of active agent to make a dosage form with the desired controlled release characteristics. Thus routine experimentation would lead one of ordinary skill in the art to arrive at the percentages as claimed, because Almarrason teaches using high doses of topiramate.

Claims 31, 33-37, 48-53, 56-57, 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Almarsson et al US 6699840 in view of Bhatt et al. US 6368626.

Almarsson discloses oral dosage forms of topiramate with excipients, such as polyvinyl pyrrolidone and hydroxypropyl methylcellulose (col. 18, lines 13-15, 47, 56-57). The reference also teaches using lubricants like polyethylene glycol (col. 19, line 41). The reference further teaches topiramate in controlled release dosage forms. Such dosage forms are formulated using hydroxypropylmethyl cellulose, and osmotic systems, such as OROS® (Alza Corporation) (col. 21, lines 25-35). The reference

teaches the amount of topiramate in the composition can range from 10 mg-1000 mg (col. 17, lines 60-63). The reference further discloses a specific dosage form of their invention to comprise "a wall defining cavity, the wall having an exit orifice formed or formable therein and at least a portion of the wall being semipermeable; an expandable layer located within the cavity remote from the exit orifice and in fluid communication with the semipermeable portion of the wall; a dry of substantially dry state drug layer located within the cavity adjacent the exit orifice and in direct or indirect contacting relationship with the expandable layer; and a flow promoting layer interposed between the inner surface of the wall and at least the external surface of the drug layer located with tin the cavity, wherein the drug layer comprises a salt of the topiramate" (col. 22, lines 29-44). The reference also incorporates by reference US 6368626 (Bhatt), which teaches the specific dosage form, which Almarsson suggested to be adapted for use with topiramate.

Bhatt teaches the same surfactants and structural polymers as claimed by Applicant (col 12, lines 46-67, col. 13, lines 1-15). The reference also discloses a push layer comprising osmopolymers (col. 14, lines 5-25). The reference teaches a drug loading between 20-90% by weight (col. 6, line 57). The reference discloses the use of a structural polymer between 1-90% of the composition, specifically 20.3% Polyox N-80 (see example 1, line 26). The drug layer of the prior art is the center of core of the dosage form, see Figure 1 A. Example 3 discloses 20.24% Polyox-80, 3% polyoxyl 40 stearate (Myrj 52S), 2% PVP, and 63.67% polyethylene oxide in the push layer (col. 22, lines 25-35). The reference teaches a core comprising a drug composition and a push

layer comprising an osmopolymer. The dosage from also possesses a semipermeable wall and an exit orifice. The comprising language of the instant claims does not exclude the flow promoting interior wall also present in the dosage form of the prior art. The reference discloses in Example I the composition contains approx. 30% surfactant and 69% the active agent. This is a ratio of approx. 1:2. One of ordinary skill in the art would be able to determine through routine experimentation the reasonable amount of surfactant to add to maintain the desired ratio and achieve the desired release profile.

It would be obvious to one of ordinary skill to use the dosage form disclosed by Bhatt to make a controlled release osmotic dosage form of topiramate because Almarsson suggests and teaches to do so. One of ordinary skill in the art would expect that the controlled released topiramate dosage form to have a reasonable level of success because Bhatt discloses that it is suitable for a wide array of active ingredients. One of ordinary skill in the art would be motivated to make the composition because Almarsson teaches that topiramate is useful for treating epilepsy, seizures and tremors.

Response to Arguments

Applicant's arguments filed 05-15-2006 have been fully considered but they are not persuasive. Applicants argue that Almarrason does not teach the specific percentages of topiramate, surfactant, and structural polymer as claimed by Applicant. Almarrason teaches using 10-1000 mg of topiramate. Applicants have not shown that this teaching does not satisfy the percentage requirement in the instant claims. Furthemore, such a wide range of dosage amount for the active ingredient taught by Almarrason would provide sufficient motivation to one of ordinary skill in the art to

optimize through routine experimentation the amount of each ingredient to make the desired dosage form. From the teaching it is apparent that using high doses of topiramate is envisioned. It would be obvious to one of ordinary skill in the art to adjust the amounts of the solubilizing surfactant and the structural polymer based on the amount of active agent to make a dosage form with the desired controlled release characteristics. Thus routine experimentation would lead one of ordinary skill in the art to arrive at the percentages as claimed, because Almarrason teaches using high doses of topiramate.

Furthermore Bhatt is relied upon for teaches that high dose amounts of active ingredients in osmotic dosage forms are known in the art. Additionally, Bhatt teaches the structural polymers and surfactants that are claimed in the instant application. A combination of the two reference would lead one of ordinary skill in the art to the claimed dosage form, and the amounts could be arrived upon based on routine experimentation.

Claims 1-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour et al. US 6491949 in view of Almarsson et al. US 6699840.

Faour discloses an osmotic delivery device that comprises a core, the core comprises a first drug and a second drug. The first and second drug are enclosed in a semipermeable membrane (col. 1, lines 40-53). The first and second active ingredients are the same (col. 1, line 57). The first and second active agent containing devices have different rates of release (col. 1, lines 58-63). Differences in the rates of release of the same active ingredient is achieved via the type and amount of semipermeable

membrane material used as well as the type and amount of other excipients, such as structural polymers and osmoagents (col. 5, lines 18-33). The reference further discloses the use of an osmopolymer in the core of the first osmotic device and the coating of the second osmotic device (col. 5, lines 30-33). The reference discloses types of osmopolymers or swellable hydrophilic polymers (col. 6, lines 61-67 and col. 7, lines 1-22). The reference teaches discloses the delivery device comprises an exit means or passageway (col. 4, line 8). The reference discloses the use of surfactants such as poloxamers, polyvinyl pyrrolidone, etc (col. 11, lines 10-20). The reference discloses a composition that will provide a "substantially ascending" rate or release and drug plasma concentration because the reference teaches the device will deliver up to 100% of the drug over a period of 18-24 hours. As the semipermeable membrane breaks down and the drug is released the rate of release will increase and as the amount of drug released increases so will the drug plasma concentration.

Figure I discloses the composition in which the first drug layer surrounded by the semipermeable coating is contained with in the second drug layer surrounded by a second semipermeable coating, and a exit orifice is present. Instant claims do not specify how the first and second drug compositions are in communication in the core of the delivery device. The reference discloses that this type of delivery device is suitable for use with a wide variety of drugs, of those drugs, neuroleptics are listed. Topiramate is a neuroleptic drug.

One of ordinary skill would be able to determine through routine experimentation the desired percentages of first and second drug and desired ratio of surfactant to drug in the composition.

Faour teaches the structural limitations of the dosage form with the exception of the particular active ingredient.

Almarsson teaches the use of topiramate in an osmotic delivery device. (See rejection above for full discussion of Almarsson).

It would have been obvious to one of ordinary skill in the art to make an osmotic delivery device offering controlled release of an active substance such as topiramate, with a core that contains a first and second drug composition comprising the same active substance with different release profiles because Faour teaching this technology and Almarsson suggests making controlled release dosage forms comprising topiramate and further suggests using osmotic delivery devices. One of ordinary skill in the art would have been motivated to use topiramate in the dosage form because topiramate is a neuroleptic drug, and Faour teaches that neuroleptic drugs are suitable to be used in this dosage form. One of ordinary skill in the art would further be motivated to make an osmotic delivery device comprising topiramate because topiramate treats neuroleptic diseases and such a dosage form offering prolonged and controlled release of the active substance would be favorable to a patient population suffering from a neuroleptic disease.

Applicant's arguments filed 05-15-2006 have been fully considered but they are not persuasive. Applicants argue that a combination of Almarrason and Faour does not

teach the specific percentages of topiramate, surfactant, and structural polymer as claimed by Applicant. Almarrason teaches using 10-1000 mg of topiramate. Applicants have not shown that this teaching does not satisfy the percentage requirement in the instant claims. Furthemore, such a wide range of dosage amount for the active ingredient taught by Almarrason would provide sufficient motivation to one of ordinary skill in the art to optimize through routine experimentation the amount of each ingredient to make the desired dosage form. From the teaching it is apparent that using high doses of topiramate is envisioned. It would be obvious to one of ordinary skill in the art to adjust the amounts of the solubilizing surfactant and the structural polymer based on the amount of active agent to make a dosage form with the desired controlled release characteristics. Thus routine experimentation would lead one of ordinary skill in the art to arrive at the percentages as claimed, because Almarrason teaches using high doses of topiramate. Faour teaches the structural limitations of the dosage form with the exception of the particular active ingredient. Thus one of ordinary skill in the art would be motivated from the combination of the two references to make an osmotic dosage (taught by Faour) from comprising a high dose amount of topiramate (taught by Almarrason).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes
Examiner-1615

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600